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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,874	12/15/2005	Toshiya Kai	IWT-001	6777
7590 Kubovcik & Kubovcik Tha Farragut Building Suite 710 900 17th Street NW Washington, DC 20006				
04/02/2008				
EXAMINER				
KISHORE, GOLLAMUDI S				
ART UNIT		PAPER NUMBER		
1612				
MAIL DATE		DELIVERY MODE		
04/02/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/534,874

**Applicant(s)**

KAI ET AL.

**Examiner**

Gollamudi S. Kishore, Ph.D

**Art Unit**

1612

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/SG/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

The amendment dated 2-25-08 is acknowledged.

Claims included in the prosecution are 1-16.

In view of the amendments, the 102 rejections of claims over Panagi, and Tardi are withdrawn.

***Claim Rejections - 35 USC § 112***

1. Claims are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant amends claim 1 to introduce the term, 'non-modified serum albumin' in claim 1 and this term has no support in the specification as originally filed and therefore, deemed to be new matter. To bond serum albumin to a liposome, albumin has to be activated and reactive groups have to be introduced and therefore, it is modified.

Claims included in the prosecution are 1-13.

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Amended claim 1 recites three limitations as Markush members; while it is clear from b and c where albumin and PEG are attached to the liposomal surface (albumin is bonded to PEG in b and albumin and PEG are at different sites in c), it is unclear from a) where these two are bonded.

Claim 9 is a process of preparation claim and does not recite any process steps. Are 5 compounds represented by figures are Markush members?

This rejection is maintained since the claim still does not recite any process steps. Applicant introduces the term, 'a step of bonding a liposome having a compound'. However, it is unclear as to what is bonded to what. If the liposome has the compound of the specific structures what is being bonded and how it is bonded?

#### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-2, 5-6, 8, 14 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Kamps (BBA, 1996) of record.

Kamps discloses liposomes, which have both albumin and PEG, are bonded (abstract, Materials and Methods). Instant claim 2 simply recites a physiologically active substance and therefore, the reference, which teaches the internalized buffer, meets the requirements of instant claim.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that Kamps discloses the use of albumin derivatized with cis-aconitic anhydride. Applicant is incorrect in this statement. Kamps on col. 1, page 185 uses both HSA and AcO-HAS (2.2.3). On col. 1, page 184 Kamps clearly states "In this paper we describe the preparation of liposome / conjugates of native HAS and of HSA partially derivatized with cis-aconitic anhydride. Succinimidyl-S thioacetate was used to covalently couple the proteins to conventional or PEG containing liposomes".

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tardi (J. Immunological methods, 1997) by itself or in combination with Alexander (US 5,679,355)

Tardi discloses liposomes which have both ovalbumin and PEG on their surfaces and such liposomes are immunogenic. The liposomes further contain doxorubicin. Ovalbumin is modified with the amine reactive cross linker SPDP according to the procedures of Loughery (using N- (3-(2-pyridyldithio) propionyl) phosphatidylethanolamine), which is cited of interest (abstract, Materials and Methods,

Figure 1). Tardi however, does not teach the binding of serum albumin. the use of serum albumin instead of ovalbumin would have been obvious to one of ordinary skill in the art since a similar binding occurs. One of ordinary skill in the art would be motivated to use serum albumin instead of ovalbumin because of the equivalency between ovalbumin and serum albumin in terms of immunogenicity taught by Alexander (col. 4, lines 51-56).

8. Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zalipski (6,180,134) in view of Kamps (BBA, 1996) or vice versa.

Zalipsky while disclosing liposomal formulations wherein the liposomal surface is attached to both PEG and protein teaches that the protein coupled to PE-PEG maleimide was much higher than either the MPB maleimides (Fig. 9; col. 11, line 62 through col. 13, line 10).

Kamps discloses liposomes, which have both albumin and PEG, are bonded (abstract, Materials and Methods).

The attachment of serum albumin taught by Kamps as the protein in Zalipsky would have been obvious to one of ordinary skill in the art with a reasonable expectation of success since albumin is a protein and one would expect similar attachment. Alternately to attach albumin to PEG-PE of the liposomes of Kamps would have been obvious to one of ordinary skill in the art since more albumin can be attached as taught by Zalipsky and because more protein can be attached as taught by Zalipsky.

The reference of Tagawa (5,264,221) is cited of interest.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Krass Frederick can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1612

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gollamudi S Kishore, Ph.D/  
Primary Examiner, Art Unit 1612

GSK